

REMARKS

With entry of this amendment, former claims 1, 2, 4-6, 9-19, 21-23, 25-42 remain pending, and new claims 59-69 have been added. Independent claim 1, along with its dependent claims 2, 4 and 9-15 have been amended as discussed at the interview with the Examiner on September 15, 2008. Original claims 5-6 and 16 also depend from claim 1. Independent claim 18 and its dependent claims 19, 21-23 and 25-42 remain pending, as previously amended or originally presented. New independent claim 59 and its dependent claims 60-69 have been added. The amendments and new claims do not present new matter, particularly considering that that there is no requirement that a claim amendment or new claim must be “word for word” as described in the specification. *See, e.g.*, claims as filed; Figs. 1A-2B (illustrating separate aperture 132 for filter 120 and recess 134 for data storage device 130). Reconsideration and allowance of the application, as amended, are respectfully requested.

I. The “Finality” of the Office Action mailed August 1, 2008, should be withdrawn

As a preliminary matter, and as discussed and acknowledged by the Examiner and his supervisor (Ms. Gakh) during the interview on September 15, 2008, the finality of the current office action should be withdrawn, as the basis of the claim rejections over Morrison (even if in part) are not tenable, since it was previously established during prosecution of the application that Morrison is not prior art under 102(e). This is further discussed herein with respect to the rejections themselves.

II. Withdrawn Rejections

Applicant acknowledges that the following rejections have been withdrawn:

- A. Rejection of claims under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Publication No. 2002/0045272 A1 to McDevitt (hereafter “McDevitt”).
- B. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt.
- C. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of U.S. Patent No. 5,219,294 to Marsh (hereafter “Marsh”).
- D. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of U.S. Patent No. 5,935,426 to Giordano (hereafter “Giordano”). Applicant notes that Giordano is no longer cited to reject any claim.

Applicant also acknowledges that McDevitt was previously cited with respect to claims 1, 2, 4-6, 11, 12, 14-15-19, 21-23, 29-31, 33-43, 57 and 58, but is now cited only with respect to dependent claims 38 and 42.

III. Claims 1, 2, 4, 11-12 and 14-16 Are Patentable Over Somack

Independent claim 1 and dependent claims 2, 4, 11-12 and 16 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Publication No. 2003/0098271 A1 to Somack *et al.* (hereafter “Somack”). Claims 14-15 and, again, claim 16 stand separately rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack. However, as was discussed at the interview on September 15, 2008, Applicant respectfully submits that Somack does not teach or suggest the apparatus of claim 1, as amended herein.

In particular, claim 1, as amended herein, recites an apparatus for use in preparing a biological specimen samples, including a tray defining a plurality of apertures for holding respective biological specimen filters to be used for collecting portions of respective biological specimen samples to be examined, and a data storage device attached to or positioned within the tray, wherein data related to the respective filters is stored in the data storage device.

It is alleged in the Office Action with reference to para. 10 of Somack that the cited reference discloses a “sample tray 50” configured to be processed by a workstation. Office Action (p. 2). It is also alleged that Somack paras. 9 and 10 describe a tray comprising a bar code associated with each aperture for storing data related to the filter, such as the type of filter used to immobilize the sample and the test to be performed on the sample. Office Action (p. 2). However, this is not what is actually described by Somack.

Beginning with para. 9, the cited section of Somack explains that the “devices” of the present invention can be bar-coded for identifying the type of membrane, type of pre-loaded agent, intended application, and/or for sample identification. Reference to such “devices” in para. 9 refers to biological sample purification devices, which have a tubular body, first and second ends, and a species-immobilizing filter that is secured within the tubular body. Somack (para. 6) (“biological specimen purification devices”; “each device...”); (para. 7) (“Each device further includes a removable cap...”); (para. 8) (“multiple device and array tray system”). Paras. 11, 29 and 67 of Somack also refer to a biological sample purification device or a capsule device, and as explained in para. 67, the capsular device 8 has a tubular body 10 and a filter 20.

Thus, the “different types of devices” that can be bar-coded mentioned in para. 9 of Somack refer to the sample purification devices or capsules, *not tray apertures used to hold specimen filters or the filters themselves*. Accordingly, the cited section of Somack is not related to a tray defining a plurality of apertures for holding a respective plurality of filters, or a data storage device, wherein data related to the respective filters is stored in the data storage device, as required by amended claim 1.

In page 2 of the Office Action, it is alleged that the “plate system 50” is configured to be processed by a work station and cites para. 10. Applicant notes that with reference to Figs. 7-11, Somack describes a “plate system 50” that includes a “plate 58”. The plate 58 defines holes 52 for a filter 54. Somack (para. 74). Somack also refers to a different component as an “array tray 22.” The tray 22 defines holes 32 for capsular devices 8. Somack (paras. 69-72). Each capsular device 8 includes a tubular body 10, caps 12, 16 and a filter 20 that is secured to the inner surface of the tubular body 10. Somack (paras. 67-68). Thus, Somack refers to a tray 22 and a plate system 50 as different components and discusses capsules 8 in the context of a tray 22, not the plate system 50. Accordingly, para. 10 of Somack actually refers to providing a “tray” capable of automation in robotic work stations, not a plate or plate system 50. Notably, the sections of Somack that describe the plate system 50 and plate 58 (paras. 74-78) do not even refer to a “tray 22” or “automation.” Moreover, para. 79 of Somack refers to methods of using a capsule and tray assemblies in automated laboratory workstations. As explained above, such capsule 8 and tray 22 assemblies are described with reference to Figs. 1-6, not Figs. 7-11 (which relate to a plate assembly 50).

Thus, it is respectfully submitted that the position taken in the Office Action that the Somack plate assembly 50 is configured to be processed by a work station as described in para. 10 is not what is actually disclosed by Somack. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic

necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

It is further alleged in the Office Action that para. 60 of Somack describes a tray comprising a bar code associated with each aperture for storing data related to the filter, such as the type of filter used to immobilize the sample and the test to be performed on the sample. Office Action (p. 2). However, Somack para. 60 refers to a barcode of a capsule or sample purification device, and a barcode on the holding tray. Regarding a barcode of the capsule 8, claim 1 recites a tray defining a plurality of apertures for holding a respective plurality of filters, and a data storage device that stores data related to the filters. However, as explained above, the capsule 8 described by Somack has a tubular body 10 and a filter 20 therein. While the filter 20 may be inside of the tubular body 10, tray recesses actually hold the tubular body 10 of the capsule 8, not the filter 20 contained therein. Further, with respect to the “plate assembly 50” (Figs. 7-11), Somack is silent as to a data storage device positioned within a recess. Somack is silent as to barcodes on the filters 54. The Office Action is also silent with regard to these matters, consistent with the deficiencies of Somack.

Regarding a barcode on a holding tray, Somack explains that the bar-codes on the holding tray correspond to “capsule positions” rather than data related to a filters. The position of a capsule 8 is not data related to a filter and does not, for example, identify the a test that is compatible with the filter, a specimen that is compatible with the filter, whether the filter has expired, or processing step parameters involving the filter. As another example, various different filters having different attributes may be located within a given capsule position, but the capsule position would not provide any such information to differentiate one filter from another. Further, Somack does not discuss filters 54 of the “plate assembly 50” (Figs. 7-11) in this context. The Office Action is also silent in this regard, consistent with the deficiencies of Somack.

Claim 1, therefore, is fundamentally different than the very limited disclosure provided by Somack. In view of these deficiencies, Applicant respectfully submits that independent claim 1 is patentable over Somack. Dependent claims 2, 4-6 and 9-16 incorporate the same limitation as claim 1 and, therefore, are patentable over Somack for at least these same reasons. Accordingly, Applicant respectfully requests that the rejection of claims 1, 2, 4, 11-12 and 14-16 over Somack be withdrawn.

IV. Claims 5, 6, 18, 19, 21-23, 29-31, 33-35 and 39-41 Are Patentable Over Somack and Morrison

Independent claim 18, claims 5 and 6 (which depend from claim 1), and claims 19, 21-23, 29-31, 33-35 and 39-41 (which depend from claim 18) stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of U.S. Publication No. 2004/0126281 A1 to Morrison (hereafter “Morrison”).

Applicant notes that a Declaration of Patrick Guiney Under 37 C.F.R. §1.131 was submitted on June 11, 2007, together with Exhibits A-C, and addressed claims 6, 18, 23, 29, 31, 35, 39 and 40. Thus, the current rejection of these claims is improper.

A Supplemental Declaration of Patrick Guiney under 37 C.F.R. §1.131 that includes the annotations of the first Declaration and additional annotations relating to claims 5, 18, 19, 21, 22, 30, 34, 41, 43 and 48 is submitted with this Amendment. The rejection of these claims is moot in view of the Supplemental Declaration of Patrick Guiney under 37 C.F.R. §1.131, swearing behind Morrison, which is entitled to a priority date of August 26, 2003 under §102(e).

The supporting exhibits A-C of the Supplemental Declaration show that the subject matter of at least claims 1, 3, 5, 6, 12, 18-23, 29-31, 33-37, 39-41, 43, 51-55 and 58 was conceived by Patrick Guiney prior to August 26, 2003. For the Examiner’s reference, Applicant respectfully submits additional copies of Exhibits A and B that include hand written numbers identifying sections of exhibits that expressly and/or inherently describe, relate to, and/or support various claims (identified by these claim numbers).

Accordingly, Applicant respectfully requests that the rejection of claims 5, 6, 18, 19, 21-23, 29-31, 33-35, 39-41, 43 and 58 under 35 U.S.C. §103(a) based on Somack and Morrison be withdrawn.

V. Claims 25-28, 36 and 37 Are Patentable Over Somack, Morrison and Marsh

Dependent claims 25-28, 36 and 37 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Morrison and Marsh.

Applicant respectfully requests that the rejection be withdrawn in view of the Supplemental Declaration of Patrick Guiney Under 37 C.F.R. §1.131 as discussed in Section IV, which swears behind Morrison.

VI. Claim 32 Is Patentable Over Somack, Morrison and Crosby

Dependent claim 32 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Morrison and further in view of U.S. Patent No. 6,770,487 to Crosby (hereafter “Crosby”).

Applicant respectfully requests that the rejection be withdrawn in view of the Supplemental Declaration of Patrick Guiney Under 37 C.F.R. §1.131 as discussed in Section IV, which swears behind Morrison.

VII. Claims 38 and 42 Are Patentable Over Somack, Morrison and McDevitt

Dependent claims 38 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Morrison and further in view of McDevitt. .

Applicant respectfully requests that the rejection be withdrawn in view of the Supplemental Declaration of Patrick Guiney Under 37 C.F.R. §1.131 as discussed in Section IV, which swears behind Morrison.

VIII. Claim 13 Is Patentable Over Somack and Crosby

Dependent claim 13 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Crosby. Crosby is cited for the limited purpose of allegedly disclosing “the stored data indicating whether the filter has expired.” Crosby, however, does not cure the above-discussed deficiencies of Somack. Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of independent claim 1 and dependent claim 13.

Crosby describes a strip test assay (not a filter) that has a machine-readable information such as a bar-code 4. The strip test assay has a sample zone 1, a test zone 2 and an optional quality control zone 3. Crosby (col. 3, lines 34-35; col. 4, lines 11-21). Crosby explains that the machine-readable information includes information of an “expiration date” but does not explain to what the expiration date relates. The very limited disclosure does not disclose, teach or suggest that the expiration date is an expiration date of a filter as recited in claim 13. The Office Action is also understandably silent in this regard. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact

that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

Accordingly, Applicant respectfully requests that the rejection of claim 13 under 35 U.S.C. §103(a) based on Somack and Crosby be withdrawn.

IX. New Claims 59-69 Are Patentable Over the Cited References

New claims 59-69 incorporate the elements and limitations of independent claims 1 and 18, therefore, are believed novel and patentable over the cited references, individually and in combination, for at least the same reasons.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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